

(19) World Intellectual Property Organization
International Bureau



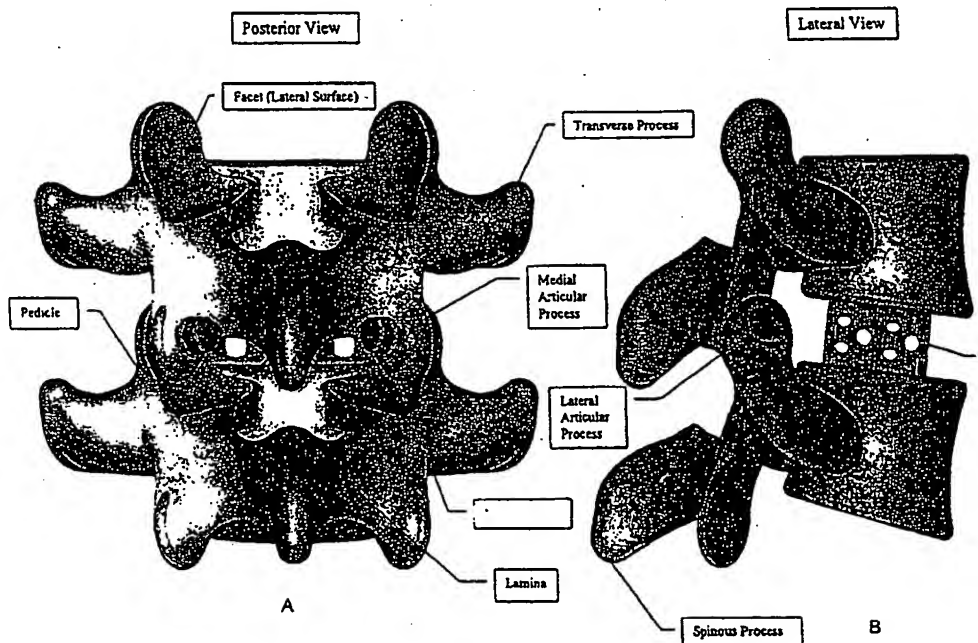
(43) International Publication Date
2 May 2002 (02.05.2002)

PCT

(10) International Publication Number
WO 02/34120 A2

- (51) International Patent Classification⁷: A61B (74) Agent: DANYKO, Richard, J.; Dreier & Baritz LLP, 499 Park Avenue, New York, NY 10022 (US).
- (21) International Application Number: PCT/US01/49661
- (22) International Filing Date: 26 October 2001 (26.10.2001) (81) Designated States (*national*): AU, CA, CN, JP, MX.
- (25) Filing Language: English (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).
- (26) Publication Language: English
- (30) Priority Data: 09/698,721 27 October 2000 (27.10.2000) US Published: — without international search report and to be republished upon receipt of that report
- (71) Applicant: BLACKSTONE MEDICAL, INC. [US/US]; 90 Brookdale Drive, Springfield, MA 01104 (US).
- (72) Inventor: DUDASIK, Michael; 29 Daily Street, Nutley, NJ 07110 (US).
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: FACET FIXATION DEVICES



(57) Abstract: The present disclosure is directed to devices used in surgery for joining together bone and/or tissue, such devices typically being inserted into a hole created in the bone and/or tissue. Such devices including implants, delivery instruments, and graft retaining aids.

BEST AVAILABLE COPY

WO 02/34120 A2

FACET FIXATION DEVICES

FIELD OF THE INVENTION

The present invention is directed to devices that are used to facilitate post-operative bone-to-bone fusion, tissue-to-bone fusion and particularly, bone fusion between two adjacent vertebrae.

BACKGROUND OF THE INVENTION

Vertebral disc degeneration has been associated with back pain and motor function loss. Loss of disc space height, extrusion of disc material, and translation of the vertebrae can result in compression of the spinal cord and nerve roots. One prescriptive treatment is to stabilize the vertebral bodies through fusion of adjacent vertebrae within the spinal column.

An operative technique of spinal column fusion employs inter-vertebral body cages. Available in different configurations from several manufacturers, the cage is inserted between two vertebral bodies in order to restore space between the discs. The device is filled with bone graft to promote fusion between the vertebrae. Access holes around the periphery of the cage provide intimate contact between the graft and host bone. The cages are typically inserted from the back (posterior) or front (anterior) aspects of the spinal column. The anterior approach involves laparoscopic methods.

Stabilization of the fusion site is advantageous in the early post-operation period. Similar to fracture healing, new bone is overlaid between the vertebral bodies, using the graft material as a lattice. Using cages as stand alone devices has met with limited success for the reason that immediate stabilization is not always guaranteed. For this reason, supplemental fixation is becoming more commonplace.

One current stabilization technique employs the placement of fixed translaminar screws into a hole drilled through adjacent vertebrae. Figures 1A and 1B show typical lumbar vertebra in which translaminar screws are driven across the facet joint, effectively locking the two vertebra in place while allowing for the four types of spine motion: forward flexion, backwards extension, axial torsion, and lateral flexion.

In an operative technique for preparing the screw hole shown in Figure 2, a hole is drilled through the spinous process, through the lamina, and across the facet. In another operative technique shown in Figure 3, a slightly higher angle is employed in drilling a hole through the spinous

process, along the top of the lamina, and across the facet. In another operative technique shown in Figure 4, the drill is angled between adjacent spinous processes and a hole is drilled directly across the facet into the bone of the pedicle/transverse process. In all cases both facet joints are fixed, the screws crossing at the midline. These approaches require a 3"-4" posterior incision along the patient's midline. Frequently, additional stab wounds are required in order to approach with the drill at a low enough angle for proper screw placement.

There is an ongoing need to provide for a facet fixation device that can be delivered simply, accurately, and quickly, while providing performance that is superior or equal to that of screw fixation.

U.S. Patent nos. 5,964,769 and 5,935,133 (sharing the same disclosure) disclose a surgical cable system and method for securing surgical cable around a portion of a human element, such as bone. The surgical cable system may include a connector and a tensioner. The connector may be adapted to hold a pin, positionable within the connector, such that the pin may secure the cable within the connector. The pin may be repositioned, after securing the cable, to allow the cable to move freely through the connector. The cable may be oriented within the connector such that the ends of the cable are perpendicular or parallel with respect to each other. The tensioner is preferably adapted to vary the tension of the cable. The cable may be passed through the connector, around a portion of a human bone, and back through the connector. The cable may be tensioned by use of the tensioner and secured into position within the connector.

U.S. Patent no. 4,611,581 discloses an apparatus for straightening spinal columns. In one embodiment, inserts are provided which are engaged by force transmitting members. The inserts are expanded into gripping engagement with the underside surfaces of the holes formed in the vertebrae.

SUMMARY OF THE INVENTION

The present invention is directed to fixation devices used in the stabilization of adjacent bones, adjacent tissue and bone wherein the stabilization occurs at a site where fusion is desired. For instance, in the case of adjacent vertebrae, an intervertebral graft cage may be inserted between the vertebrae in order to promote the growth and fusion of bony material. Supplementary fixation

devices are placed in holes drilled through the medial articular process and the pedicle of adjacent vertebrae.

In one aspect of the invention, the devices are comprised of an arrangement having a first expandible sleeve and a second expansion component that expands the sleeve when placed inside it. The arrangement is long enough to traverse two adjacent vertebrae through which a hole has been drilled. The sleeve is placed within the hole, and the sleeve expands when the expansion component is placed inside it. The arrangement forms a firm fit with the bone surrounding the drill hole, locking the fixation device in place. The expansion occurs at an end of the device, both ends of the device, in the middle of the device, and other possible variations on these arrangements. The device may be provided with teeth-like protrusions which bear into the bone in the area around the drill hole, which provides an added measure of fixing the bone into place.

Yet another embodiment of the present invention is an inserter suitable for delivering at least some of the devices discussed in the above paragraph to the interior of a drilled hole. The inserter has a drive rod movably mounted within a body and having a length longer than the body, the body housed within a sleeve that is movably mounted over the body, the body being provided with a slit distal tip, the distal tip having an inward facing projection; wherein the slit distal tip is allowed to fl outwardly when the sleeve is moved away from the slit distal tip.

Yet another embodiment of the present invention is directed to a graft retaining device for facilitating the growth of bone material in the space between adjacent vertebrae, the device having a body, which could be cylindrical in shape, provided with a length and an opening extending through the body. On one side, the body has a slit extending in the length direction. The body is further provided with a non-smooth surface having a series of annular ribs and adjacent grooves. In use, the opening is loaded with bony material. The through holes permit contact between the vertebrae and the graft material packed inside, facilitating bone growth. The graft retaining device is inserted in a collapsed state, and expanded out to the drill hole walls. A further aspect of the invention relates to a delivery instrument for inserting this graft retaining device in a hole created in bone or tissue.

For simplicity's sake, as used herein the words "tube" or "tubular" are used with the intention of encompassing a hollow structure of any shape, whether cylindrical or not.

BRIEF DESCRIPTION OF THE DRAWINGS

Figures 1A, 1B shows a posterior and lateral view, respectively of prior art fixation devices

Figures 2, 3, and 4 show prior art techniques for selection the location for a drill hole.

Figure 5A shows a perspective view of the components of an embodiment of the present invention.

Figure 5B shows a perspective view of the Figure 5A embodiment prior to insertion.

Figure 5C shows a perspective view of the Figure 5B embodiment after insertion.

Figures 6A-6C show another embodiment of the present invention.

Figures 7A-7C show yet another embodiment of the present invention.

Figures 8A-8D show yet another embodiment of the present invention.

Figures 9A-9C show yet another embodiment of the present invention.

Figure 10 depicts an embodiment of a graft retaining aid.

Figures 10A to 10E show the placement of the graft retaining device within a hole that has been drilled across two facets.

Figures 11A-11C show an embodiment of a surgical implant.

Figures 12A-12D show side plan and cross sectional view s of the Figures 11A-11C surgical implant.

Figures 13A-13B show alternatives to the Figures 11A-11C embodiments.

Figure 14A shows a perspective view of the an embodiment of an inserter.

Figure 14B shows a perspective view of the distal tip of the inserter shown in Figure 14A.

Figure 15 shows the implant loaded into the inserter.

Figure 16 shows the inserter actuated to expand the implant.

Figure 17 shows the implant released from the inserter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Expandible Mechanisms

Figure 5A shows an embodiment of the invention in which an expansion sleeve is placed over an inner expander. The expander bolt 10 of this embodiment is comprised of the exterior sleeve 12, inner expander 14, a nut 16, and optionally a locknut 18.

The sleeve 12 has a flange 24 on its medial end 26 of the shaft 27. The flange has a series of tangs 28, which are sharpened teeth, that penetrate into the bone in the area surrounding the drill hole when the assembly is inserted and tightened. This prevents the assembly from rotating after it has been inserted.

At its lateral end 30 of shaft 27, the sleeve 12 is provided with a tapered profile where the diameter gradually increases as the lateral end is approached, so that the cross sectional area of opening increases as the lateral end is approached. The sleeve 12 is further provided with discontinuations 32 on the exterior of the shaft. As shown in Figures 5A-5C, the discontinuations may be slot-shaped openings. The slots extend from the lateral end 30 to approximately the mid point of the length of the shaft 27. Sleeve 12 is also provided with annular ridges 29 on its surface which increase resistance to removal when the assembly is fixed within the drill hole.

Expander 14 is provided with a first cylindrical zone 34 having a substantially constant thickness along the length of the zone. This zone is of a thickness that passes freely into the interior 22 of the sleeve 12. Conical zone 36 of expander 14 has a gradually increasing thickness as the lateral end 38 of the expander is approached. At least a portion of the conical zone has a cross sectional area that is greater than the cross sectional area of the interior of the sleeve, so that when this portion of the conical zone enters the sleeve, the sleeve deforms and is forced outwardly (see Figures 5B and 5C). When the assembly is in place it engages the bone surrounding the drill hole.

A number of pins 40 extend outward from the expander. The pins 40 are spaced around the exterior of the expander 14 and are dimensioned to fit within the slots 32 formed on the sleeve 12.

The expander is further provided with threaded portion 35 along the cylindrical zone 34. The threaded portion 35 extends through the sleeve 12 (see Figure 5B) and mates with threads on the interior of the nut 16 and optional locknut 18.

In operation, the expander 14 is placed within the sleeve 12. This arrangement is then placed within the drill hole extending through adjacent vertebrae, with the flange bearing against the exterior of one of the vertebrae. When in place, the nut is tightened, pulling the expander 34 through the sleeve 12. As the conical zone 36 is pulled through the sleeve 12 by the tightening of the nut 16, the sleeve expands at its lateral end, thereby engaging the bone located at the interior of the drill hole. During the tightening of the nut, the tangs located on the flange 24 of sleeve 12 bear

into the bone. Ridges 29 on the exterior of the sleeve provides an additional measure that contributes to securing the assembly to the bone.

A variation on this embodiment is shown in Figures 6A-6C. Sleeve 12 is provided with slots 42 located on the medial end of the shaft which extend onto the flange 24. The sleeve 12 is provided with a tapered profile shown at 12A on the interior wall at the medial end so that the cross sectional area increases as the medial end of the sleeve is approached. Nut 16 is provided with a conical extender 44. The extender 44 has a tapered profile that gradually widens from its distal end 44A to its medial end 44B. When the outer nut 18 is tightened on nut 16, the extender 44 enters the sleeve 12 and expands it outwardly at the medial end of the sleeve. Since the expander 14 shown in the figures is the same as the one described in the embodiment of Figures 5A-5C, the assembly expands at the distal end as well. Thus, in this embodiment, a second region is provided where the fixation device expands out into the bone surrounding the drill hole.

Yet another embodiment which employs bolt-like components is shown in Figures 7A-7C. This embodiment employs an expander 34 having a shaft 49 over which at least a portion 50 is threaded. Portion 52 of shaft 49 is smooth and has a substantially constant cross sectional area over its length. At its distal end 54 the expander is provided with a rounded tip 55, which may facilitate insertion through the sleeve 12. The expander is provided with a hex nut 56, which in this embodiment is integral with the shaft 49, but does not have to be. While sleeve 12 is similar to the sleeve already described, it is provided at its distal end 54 with a tapered tip. That is, the interior walls of the shaft at the distal end are tapered so that the cross sectional area of the open interior gradually decreases as the distal end is approached. At some point within the tapered tip the cross sectional area of the opening is less than the cross sectional area of the expander 34. As a result, when the expander 34 enters the tapered portion of the sleeve 12, the sleeve is expanded, so that the expanded portion of the sleeve bears against the interior of the drill hole in the vertebrae.

Figures 8A-8C show yet another bolt-type embodiment. Sleeve 12 is provided with a hollow portion 61 which defines an open interior space 60 dimensioned to receive expander 34. The interior space is threaded and mates with the threads 62 provided on the exterior of the shaft 64 of the expander 34. The threads 62 are provided along the shaft from its distal end to an intermediate point. Close to the Allen head 70, the shaft 64 is thread-less. The hollow portion 61 is provided with slotted openings that are confined to the intermediate region. That is, the slots are

defined on four sides by the hollow portion and do not open onto an edge of the expander 34. The assembly is provided with a zone which expands outwardly into the space surrounding the drill hole.

The hollow portion 61 is joined to a flange 66 provided with tangs 68. The tangs are sharp, tooth-like protrusions angled in the direction of the hollow portion 61. When the sleeve and expander are inserted into the drill hole, the tangs bear into the bone surrounding the drill hole and prevent or limit the rotation of the sleeve when the expander is threaded into the open interior space 60.

The shaft 64 of the contractor is provided with an Allen head 70 (or some other known tool head). In operation, the contractor is placed within the sleeve and the contractor is tightened. During tightening, the threaded portion of the sleeve is forced to rise towards the medial end. As the screw is tightened, head 70 compresses against the flange 66 to a point where screw rotation is halted. Further tightening forces the thread portion of the sleeve to ride up the screw, causing the ribs to deform. This causes the slotted area of the sleeve to move into the walls of the drill hole, locking the implant in place.

Figures 9A-9C show yet another embodiment in which a housing 70 having a hollow portion 72 defines an open interior space 60. A spring sleeve 74 is provided with a slotted flange 76, from which extends a hollow portion 78 having a length that extends only partially into the housing 70. A pair of protruding fingers 80, threaded on their interior surface, extend from the hollow portion. Flexible tabs 82 are provided at the end of the fingers 80 and extended outwardly, perpendicular to the direction in which the fingers extend. The fixation device further includes a lock rod 84 provided at its proximal end with an Allen head 86, from which a shaft 88 extends outwardly. The exterior of the shaft 88 is dimensioned to pass into the hollow portion of the spring sleeve 74 and threadably engage the spring sleeve and the fingers 80.

In operation, the housing 70 is placed within the drilled hole. When the spring sleeve 74 is initially inserted into the housing 70, the flexible tabs 82 press inwardly against the interior wall of the housing 70. See Figure 9B. When the spring sleeve 74 is moved through the housing 70, the flexible tabs 82 pass out of the distal end of the housing 70. The outward protrusion of the tabs 82 holds the spring sleeve 74 in place and the positioning of the arrangement is secured when the lock

rod is screwed into the spring sleeve so that the shaft passes between and immobilizes the tabs. See Figure 9C.

Aids for Facilitating Graft Retention

When employing translaminar fixation, surgeons often remove the cartilage in the facet joint and pack the area with bone graft, creating a site for bony fusion. The devices described below are inserted into the space between the joints and are packed with graft material to create a site for bony fusion. Figure 10 depicts a graft retaining aid.

The graft retaining device of this embodiment is a tube 200 having an open passageway 202 through the length of the tube with a longitudinal slit 204 provided on one side. A series of annular ribs 206 and adjacent grooves 207 provide a non smooth surface that facilitates fixation between the device and the adjoining facets. Through holes 208 permit contact between the host bone and the graft material packed inside, which facilitates fusion of the bony material.

Figures 10A to 10E show the placement of the graft retaining device within a hole that has been drilled across two facets. The delivery instrument 600 is tubular in shape and is constructed with an outer shaft 602 and an inner shaft 606. The inside diameter of the outer shaft 602 is smaller than the outer diameter of the graft retaining device 200, when the slit on the device is open, yet when the slit on the device is closed, the device fits within the outer shaft 602, which in turn fits within the drill hole. (The diameter of the device 200 is smaller than the diameter of the drill hole through the facets and the slit does not open fully, or not at all, when the device is placed in the hole.) Outer shaft 602 is provided with handle portion 603 and device-receiving portion 604. The device 200 is loaded into the device-receiving portion 604 of the outer shaft 602, which extends out from the delivery instrument 600.

The device-receiving portion 604 of the delivery instrument 600 is inserted into the hole drilled across the facets (Figure 10B), and driven in until the stop 605 on outer shaft 603 encounters the hole. Outer shaft 602 is retracted, such as by gripping handle portion 603 and pulling back on it, which causes the outer shaft to slide over the inner shaft 606, while leaving the device 200 in place (Figure 10C). The inner shaft 606 may be provided with a solid end that abuts the graft retaining device, which aids in keeping it in place when the outer shaft 602 is retracted. The outer shaft 602 is entirely retracted, leaving the device 200 within the drill hole (Figure 10D). When the outer shaft 602 is retracted from the device 20, the device expands at slit 204, as much as the size

of the drill hole permits. The device thus forms an interference fit with the walls of the drill hole (Figure 10D). The device 600 is then removed from the vicinity of the drill hole 600 (Figure 10D)

Figures 11A-11C shows a two piece fixation device 700 utilizing a pin 702 and a sleeve 704. The pin 702 (Figure 11A) is comprised of a head 706 and a tip 708 which are connected by a cylindrical shaft 710. The head may be provided with flat sides 712. Due to the size of head 706, which is greater than the size of the opening in the sleeve into which the pin is inserted, the head eventually provides a positive stop when the pin 702 is driven into the sleeve 704.

Tip 708 is provided with a rounded end 714 (Figures 12C, 12D) which facilitates the entry the expander pin 702 into the sleeve 704 and provides a smooth surface to reduce or avoid tissue irritation. Behind the spherical tip, in the direction of the shaft 710 is at least one recess 716. A plurality of recesses 716 are shown in Figure 11A. The recesses are less thick when compared to the thickness of the shaft 710. Behind the recesses, also in the direction of the shaft 710, is an undercut 718, which also is a region of reduced thickness.

Sleeve 704 (Figure 11B) is comprised of a head 720, a hollow tubular mid-shaft 722, and a distal tip 724. Head 720 has a slot 721 which receives the head 706 of the expander pin 702. Behind this is an undercut that captures an inserter instrument. One wall of the undercut is graduated to ease disengagement of the inserter. The mid-shaft 722 has a series of fenestrations 726 intended to provide an interference fit with the walls of the hole prepared in the bone or tissue. The distal tip 728 has a series of slots 730 which allow the sleeve to expand.

The interior of sleeve 704 is open so that the pin 702 can be received therein. The inner wall of the sleeve 704 near the distal tip 728 is provided with tabs 732 that project into the open space. As the pin is driven the Tabs engage the undercut on the pin. The exterior of the distal tip has fenestrations 715 that in the deployed condition create an interference fit with the walls of the prepared hole. The distal tip may also be smooth. The fenestrations of the preferred embodiment resemble a cortical screw thread. They could however be of any configuration (grooves, splines, etc.) which would provide a "bite".

Figure 11C shows a tapered portion 717 as an alternate to the fenestrations 715. Rather than cutting into bone, the taper would engage a conic shape prepared in the bone, providing a measure of resistance to pull out of the Implant.

Figures 12A, 12B, 12C, and 12D illustrate the transformation of the implant from the non-deployed, pre-expanded state to the deployed, expanded state. The sleeve and pin arrangement is inserted into the prepared drill hole in the initial, non-deployed state. In the initial, non-deployed state, in which the head 706 of the pin is situated outside of the slotted head 720 of the sleeve, the tab 732 on the inner wall of the sleeve resides within the slot 730 provided on the pin 702. In this arrangement the sleeve is in an unexpanded state. The pin 702 is then moved forward in the sleeve 704 so that the head 706 of the pin 702 is situated in the slot 721 of the head 720 on the sleeve 704. Forward movement of the pin moves the recess out from under tab, and the tab rides up on the shaft 710. Since the shaft is thicker than the recess, the abutment of the tab against the shaft expands the sleeve at the recessed region. To maintain the tab in position on the sleeve, the shaft is provided with an undercut, which is a grooved region on the shaft having a modest reduction in thickness, i.e., a thickness intermediate that of the recess 716 and shaft 710. The undercut 718 is situated where the tab will reside when the pin is fully inserted in the sleeve and the device is in the deployed state. The walls of the groove retain the tab within the undercut, insuring that the tab will remain within the groove. See, e.g., Figure 25D.

Figures 13A and 13B show alternate head configurations. In these embodiments, the slotted head of the sleeve 704 is omitted and the head of the pin is replaced by a hex head (Figure 13A), or alternatively by a smooth head (Figure 13B).

Inserters

Figure 14A shows an embodiment of the inserter 900 that can be used to insert the implant of Figures 11, 12 and 13. The inserter 900 is provided with a drive rod 906 movably mounted within a body 902, which in turn is housed within a sleeve, which moves over the body. Figure 14B shows an enlargement of the distal region 908 of the inserter 900. The body is provided with slots 910, here shown present on the lateral sides 912 of the body 902, which results in a split distal tip 908 of the body 902. Distal tip 908 is further provided with an inward facing projection 914, which extends into the groove 719 provided on the implant 700 when the implant is loaded in the body (see Figure 15). The slots 910 in the body 902 allow the body to flex as the implant is attached to the inserter.

The implant is loaded in the inserter tip is shown in Figure 15. In the loading of the implant into the inserter, as shown in Figure, the sleeve of the inserter is retracted and is out of view. When the implant is inserted into the split tip 908 of the body 902, the body 902 expands over the implant head at the slots 910. Also during the loading step, the drive rod 906 is retracted. The sleeve 904 is moved from the retracted position towards the distal tip, which applies pressure on the body, which insures that the implant cannot be displaced from the inserter.

At this point the implant is inserted into the prepared hole. The drive rod is advanced and brought in contact with the pin.

Figure 16 shows drive rod 906 moved distally to the point where the head 706 of the expander contacts the head 720 of the sleeve. At this point the implant is fully expanded against the walls of the prepared hole. Figure 17 shows the release of the inserter from the deployed implant. To effect this, the sleeve is retracted, allowing the distal tip 908 of the body to move outwardly. Further advancement of the driver rod pushes on the implant, The edges of the projection and the groove are ramped to facilitate this action. The inserter is then removed from the patient.

Movement of the drive rod through the body can be effected by providing complimentary threaded surfaces on the interior of the body and exterior of the rod. Rotating the rod will effect a linear movement of the rod, either to or away from the distal end, depending upon the direction of rotation. Alternatively, the inserter may be provided with a gun or pistol grip type instrument where the linear action of the drive rod is provided by the actuation of a pivoting handle.

The sleeve can be a separate instrument used in a previous segment of the surgical procedure. The sleeve can also be in place within the patient prior to loading / introducing the Implant. In this instance the Implant is snapped into the body, then fed through the sleeve and into the prepared hole.

The embodiments of the present invention can be constructed of any material known to be suited for constructing surgical implants. To name just a few for exemplary purposes, such materials include titanium, cobalt chromium alloy, stainless steel, plastic materials, and bioabsorbable materials.

Numerous modifications and variations of the present invention are possible in light of the above teachings. It is evident that variations on the present invention may be constructed, which, in accordance with controlling law, are still subject to the claims written in view of the preceding disclosure.

What is claimed is:

1. A fixation device for the stabilization of vertebrae when the device is placed into a hole that is cut through the medial articular process and lateral articular process/pedicle comprised of:
 - a first component having a zone provided with a width dimension;
 - a second component in the form of a tube open at its first and second ends, the tube having a width dimension less than the width dimension of the zone of the first component, wherein the second component is further comprised of a flange extending outward from the first end, the second component having a discontinuation located thereon,
 - wherein when the zone of first component is inserted in the second component, the second component expands at the discontinuation;
 - and a third component movably mounted on the first component to a position against the flange.
2. The device of claim 1 wherein the first component has first and second zones provided with a width dimension, wherein the width of the second zone is greater than the width of the first zone, the tube having a width dimension less than the width dimension of the second zone of the first component.
3. The device of claim 2 wherein the second zone of the first component has a tapered width.
4. The device of claim 2 wherein the first zone of the first component commences at a first end of the first component and the second zone of the first component terminates at a second end of the first component, wherein the width of the second zone of the first component increases as second end of the first component is approached.
5. The device of claim 1 wherein the discontinuation is a plurality of slots located at the second end of the second component.
6. The device of claim 1 wherein the flange is provided with a plurality of fenestrations extending in the length direction of the second component.

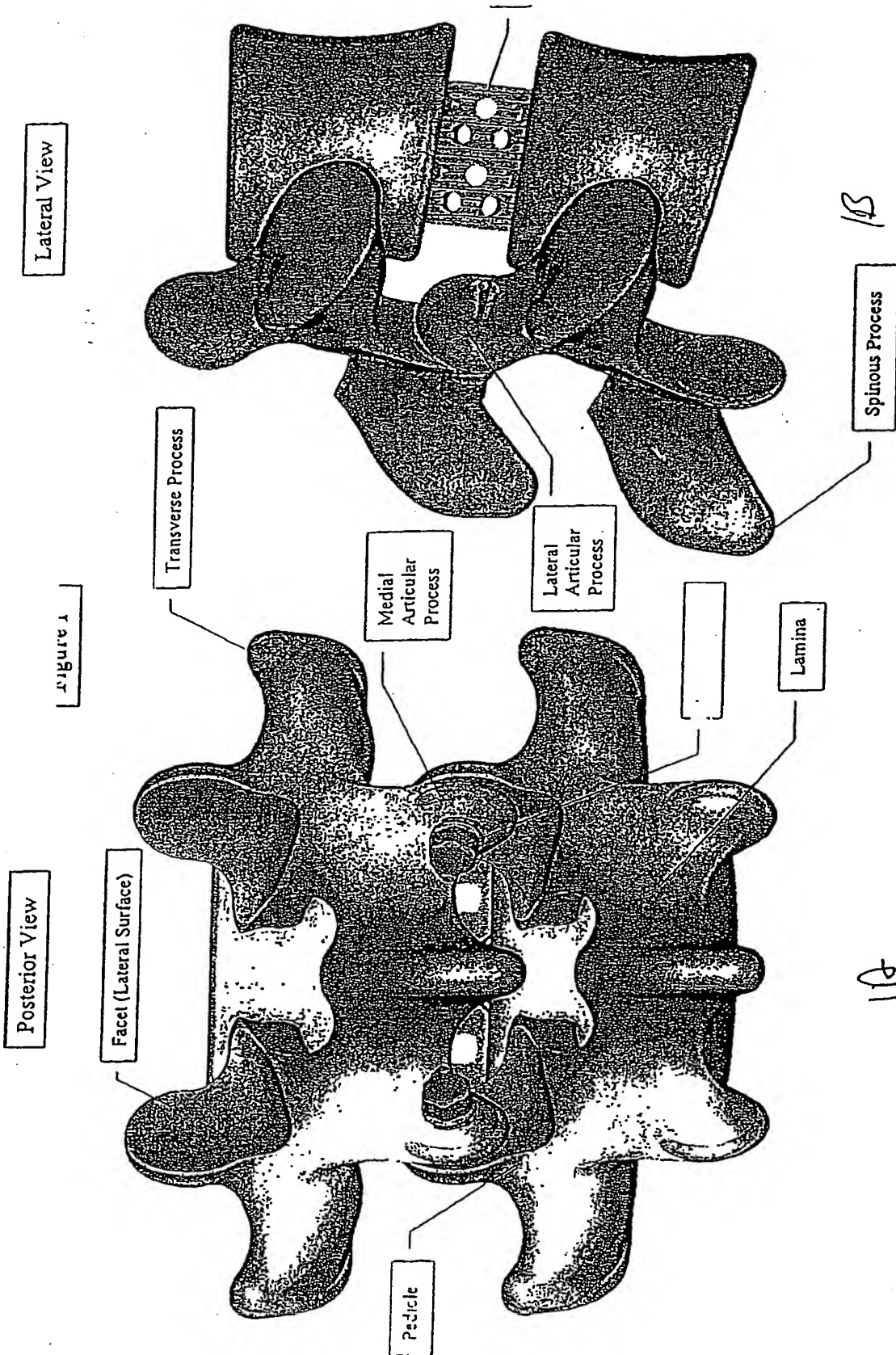
7. The device of claim 1 wherein the first component is provided with threads.
8. The device of claim 7 wherein the third component is a bolt having an threaded aperture which receives the threads located on the first component .
9. The device of claim 1 wherein the second zone is provided with an protrusion extend out from the second component, the protrusion being sized and located to pass within the discontinuation on the second component.
10. The device of claim 1 wherein the second component is provided with a fenestrated surface.
11. The device of claim 1 further comprised of an lock nut which bears against the third component.
12. The device of claim 1 wherein the second component is provided with discontinuations located on the flange and the first end of the second component.
13. The device of claim 12 wherein the third component is provided with a tapered component sized to fit within the opening at the first end of the second component.
14. The device of claim 13 wherein the opening on the second component is provided with a tapered opening to receive the tapered component.
15. A fixation device for the stabilization of vertebrae, wherein the device is placed into a hole that is cut through the medial articular process and lateral articular process or pedicle, wherein the device is comprised of:
 - a first component having a head at a first end and a body extending from the head to a second end, the body having a zone provided with a width dimension;
 - a second component in the form of a tube open at its first and second ends, the tube having a zone with a width that is less than the width of the zone of the first component, the second component having a discontinuation located thereon, wherein the second component is further comprised of a flange extending outward of the second component at the first end, wherein when the zone of first component is inserted in the zone of the second component, the second component expands at the discontinuation.
16. The device of claim 15 wherein the head is a nut.

17. The device of claim 15 wherein the body of the first component and the opening at the first end of the second component are provided with complimentary threads.
18. The device of claim 15 wherein the flange is provided with a plurality of fenestrations extending in the length direction of the second component body.
19. The device of claim 15 wherein the discontinuation is a plurality of slots located at the second end of the second component.
20. The device of claim 15 wherein the discontinuation is a plurality of slots located between the first and second ends of the second component.
21. A fixation device for the stabilization of vertebrae, wherein the device is placed into a hole that is cut through the medial articular process and lateral articular process or pedicle, wherein the device is comprised of:
 - a first component having a head at a first end and a threaded body having a length extending from the head to a second end, the body having a width dimension;
 - a second component provided with a flange located at a first end, from which a tubular portion extends, the tube defining an opening sized to receive the first component, fingers extending from the tubular portion to a second end, wherein the body and fingers are threaded on their interior surface, and flexible tabs located at the second end extending outwardly from the fingers;
 - a third component in the form of a tube sized to receive the second component, the body having a first end and a second end, a flange located at the first end, the body defining an opening through the third component.
22. The device of claim 20 wherein the second component flange is further comprised of a slot sized and located to receive a tab located on the third component flange, the tab being sized and located to fit within the slot.

23. The device of claim 20 wherein the third component flange is provided with fenestrations that extend in the length direction of the first component.
24. A graft retaining device for facilitating the growth of bone material in the space between adjacent articular processes comprised of a body having a length, an opening extending through the body, wherein the body has a slit extending in the length direction provided on one side of the body, the slit movable between an open position and a closed position, and wherein the device is biased to the open position, a non-smooth surface having a series of annular ribs and adjacent grooves, wherein the opening is loaded with bony material and the through holes permit contact between the vertebrae and the graft material packed inside.
25. A surgical implant comprised of:
a pin situated within a sleeve;
the pin comprised of a head and a tip which are connected by a midportion;
the head dimensioned to provide a stop to the movement of the midportion through the sleeve;
the tip provided with a first region of reduced thickness relative to the thickness of the midportion of the pin;
a second region of reduced thickness provided on the midportion, wherein the second region has a thickness greater than the first region;
the sleeve comprised of a head, a tubular shaft defining an interior, and a distal tip provided with at least two slots;
the interior of sleeve receiving the pin; at least one tab provided on the inner wall of the sleeve near the distal tip that projects into the space; wherein the sleeve expands at the slots provided thereon when the tab engages the second portion of reduced thickness.
26. The surgical implant of claim 25 wherein the first and second regions are adjacent to each other.

27. The surgical implant of claim 25 wherein the exterior of the sleeve has fenestrations, that, when the implant is deployed in hole that has been bored in bone or tissue, will create an interference fit with the walls of the hole.
28. The surgical implant of claim 25 wherein the exterior of the sleeve is smooth.
29. The surgical implant of claim 25 wherein the head of the pin is dimensioned to fit within a recess provided on the head of the sleeve.
30. The surgical implant of claim 25 wherein the exterior of the sleeve is provided with a tapered region.
31. The surgical implant of claim 25 wherein the head of the pin is hex nut.
32. The surgical implant of claim 25 wherein the head of the pin is a rounded surface.
33. The surgical implant of claim 25 wherein the implant is in an unexpanded state in which the tab on the sleeved is positioned within the first region of reduced thickness of the pin.
34. The surgical implant of claim 25 wherein the implant is in an expanded state in which the tab on the sleeve is positioned within the second region of reduced thickness of the pin.
35. The surgical implant of claim 25 wherein an undercut is positioned on the exterior of the sleeve in the region near the medial end of the sleeve.
36. An inserter suitable for delivering the implant of claim 25 to the interior of a drilled hole comprised of: a drive rod movably mounted within a body and having a length longer than the body, the body housed within a sleeve that is movably mounted over the body, the body being provided with a slit distal tip, the distal tip having an inward facing projection; wherein the slit distal tip is allowed to flex outwardly when the sleeve is moved away from the slit distal tip.
37. A method of inserting the surgical implant of claim 25 into a hole that has been created in bone or tissue, comprised of the steps determining whether the split distal tip is in an opened position and opening the split distal tip if it is not; loading the implant into the opened split distal tip, closing the slit distal tip onto the implant; inserting the implant into the hole; advancing the drive rod towards the split distal tip into contact with the pin of the implant, driving the pin forward to expand the sleeve, and releasing the implant from the inserter.
38. The inserter of claim 25 wherein the interior of the body and exterior of the rod are provided with complimentary threaded surfaces.

39. A delivery instrument for delivering the graft retaining device of claim 24 comprised of a tubular outer shaft sized to receive the graft retaining device and mounted over an end of an inner shaft, the outer shaft movable between a first position wherein the outer shaft extends substantially out from the inner shaft and a second position where the outer shaft extends substantially over the inner shaft.
40. The delivery instrument of claim 39 wherein the outer shaft is provided with handle portion and device-receiving portion.



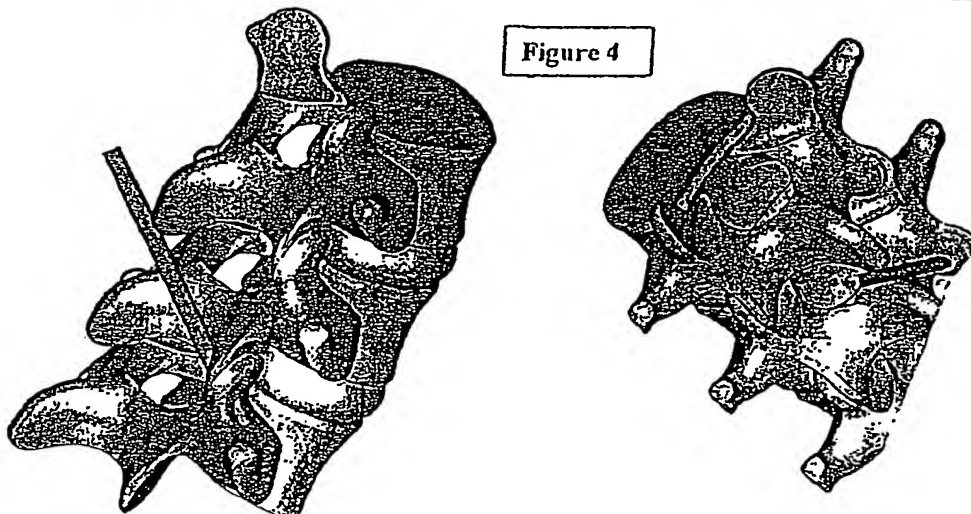
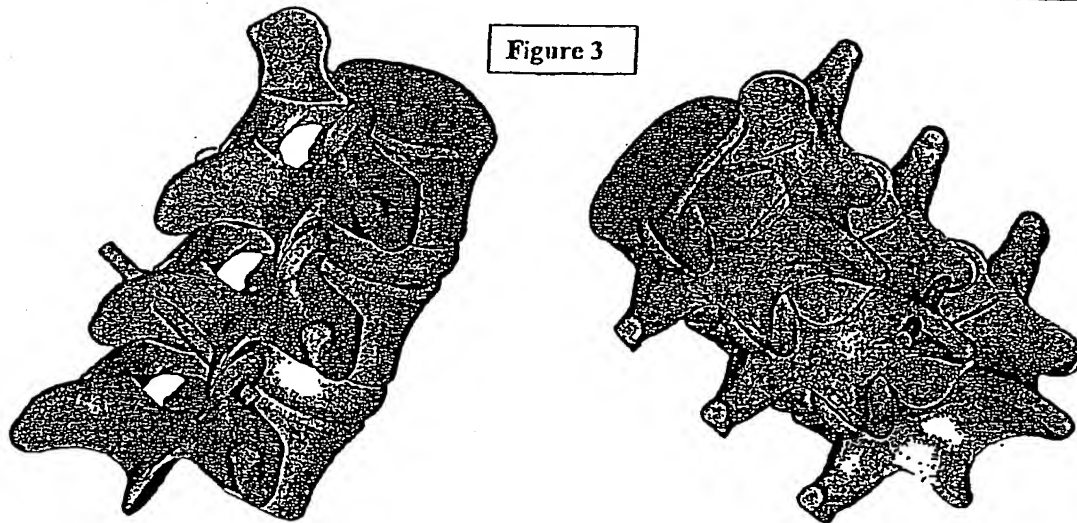
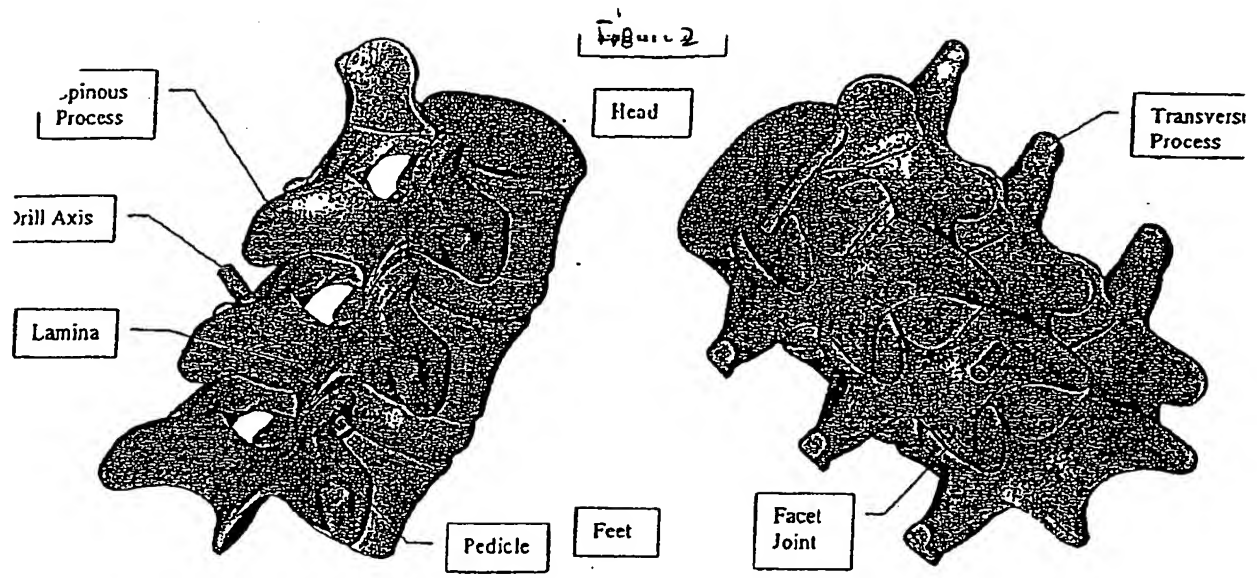


Figure 5

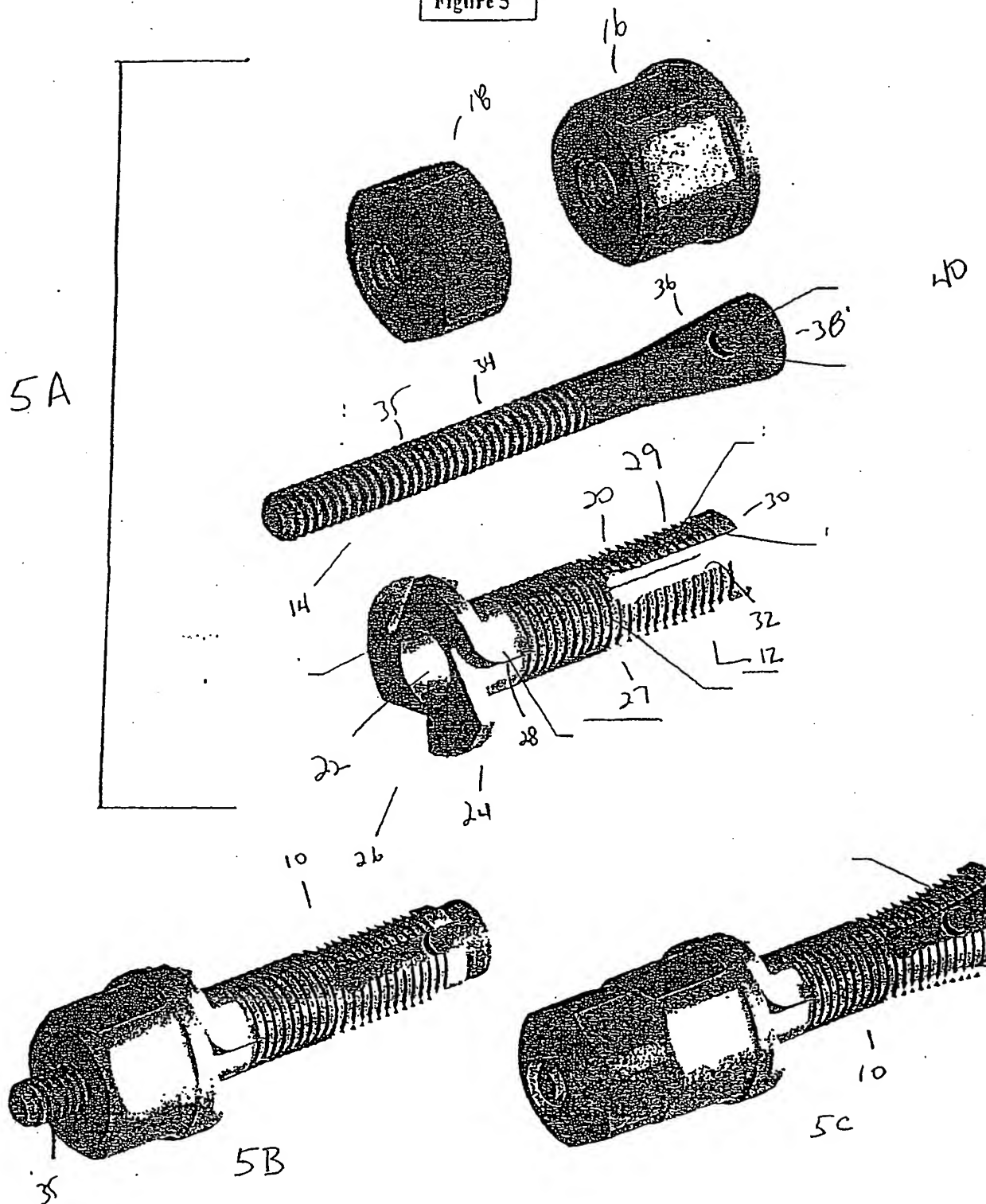


Figure 6

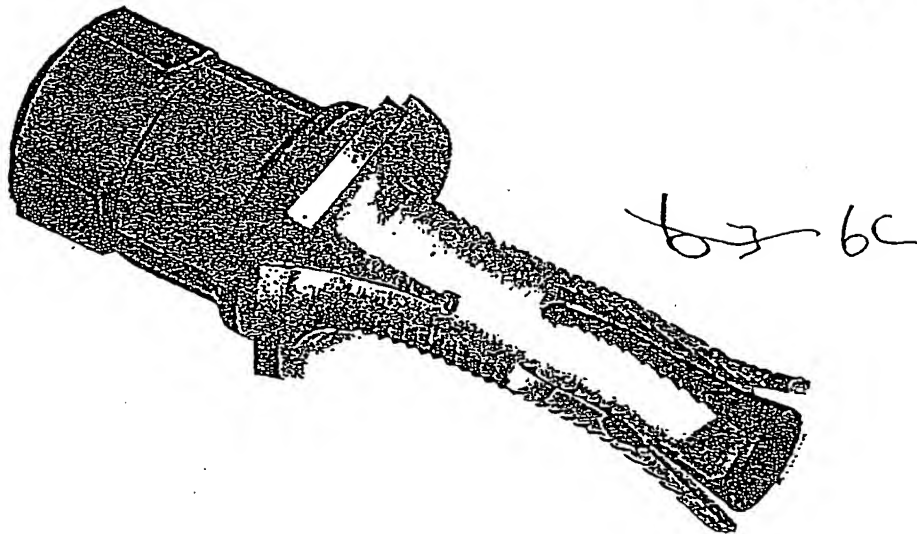
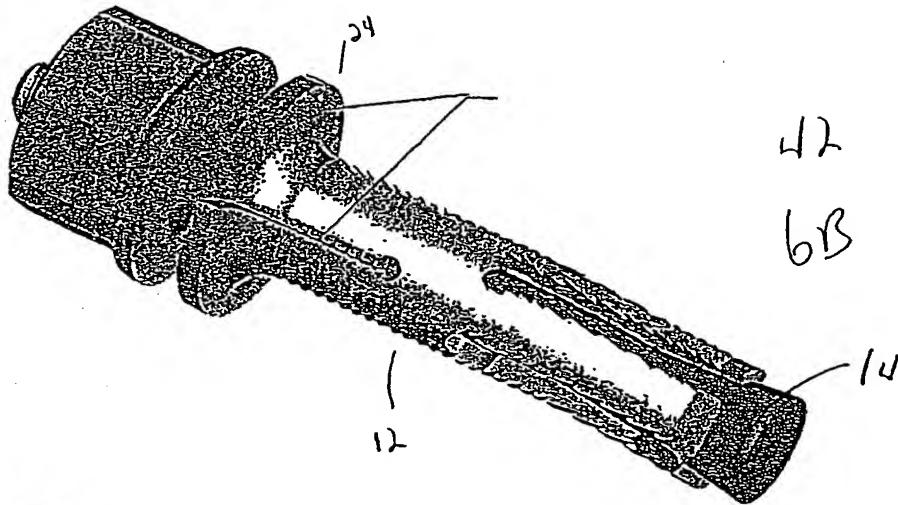
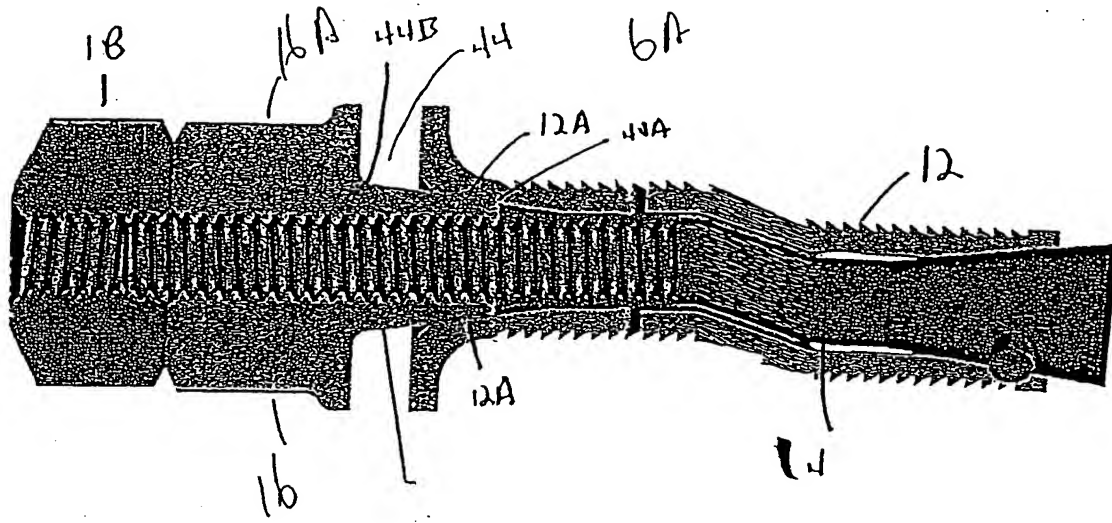


Figure 7

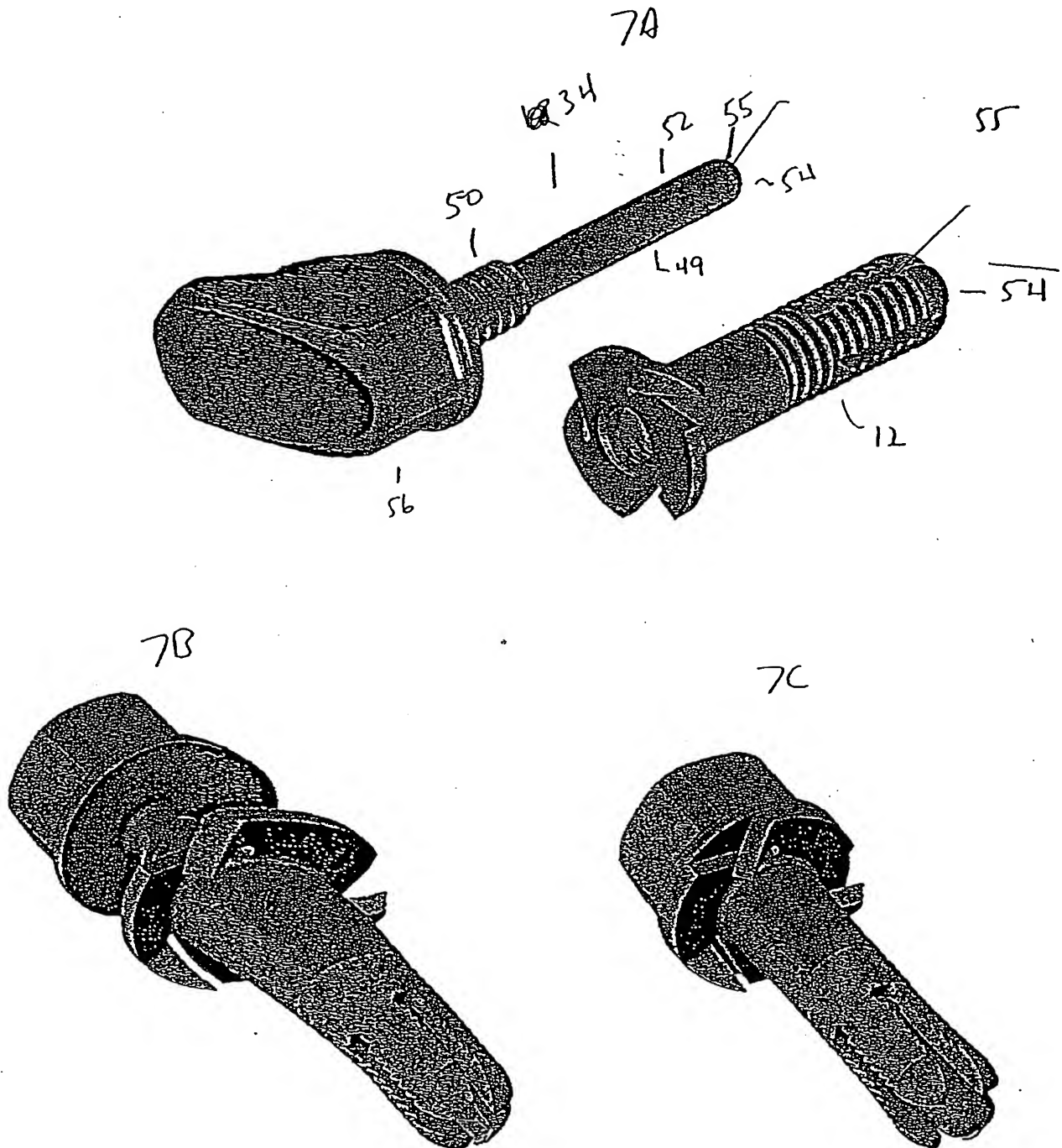


Figure 8

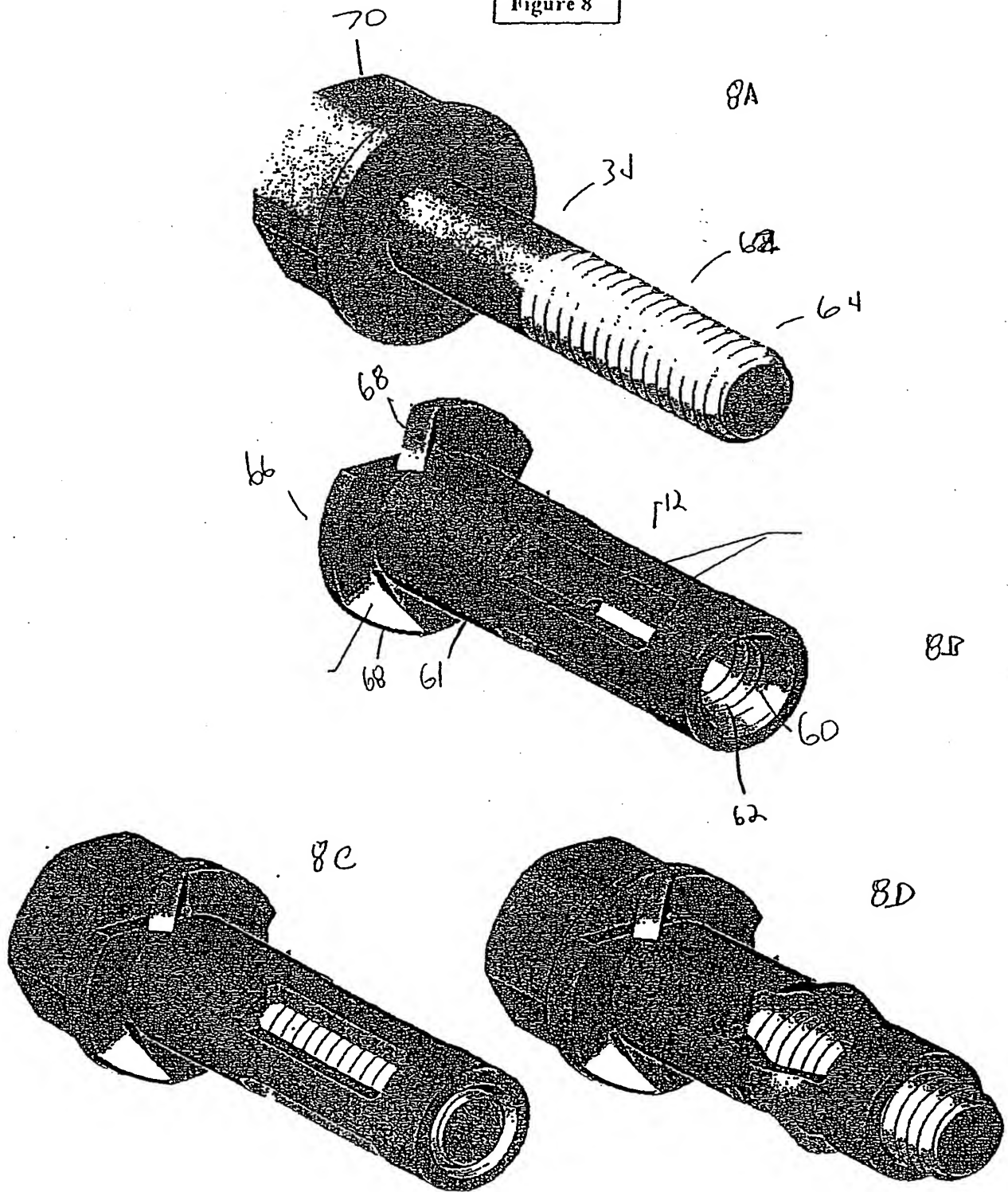


Figure 9

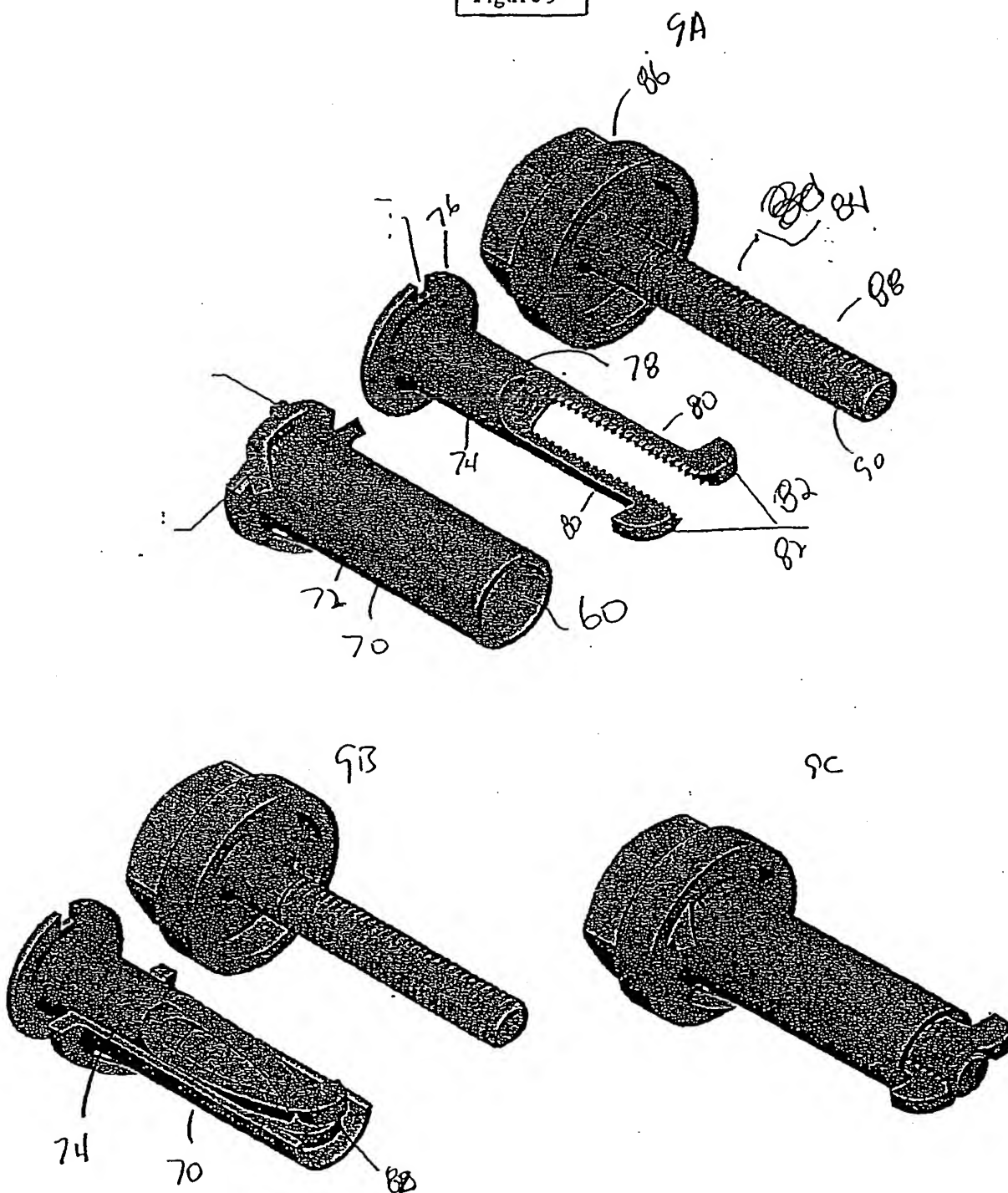
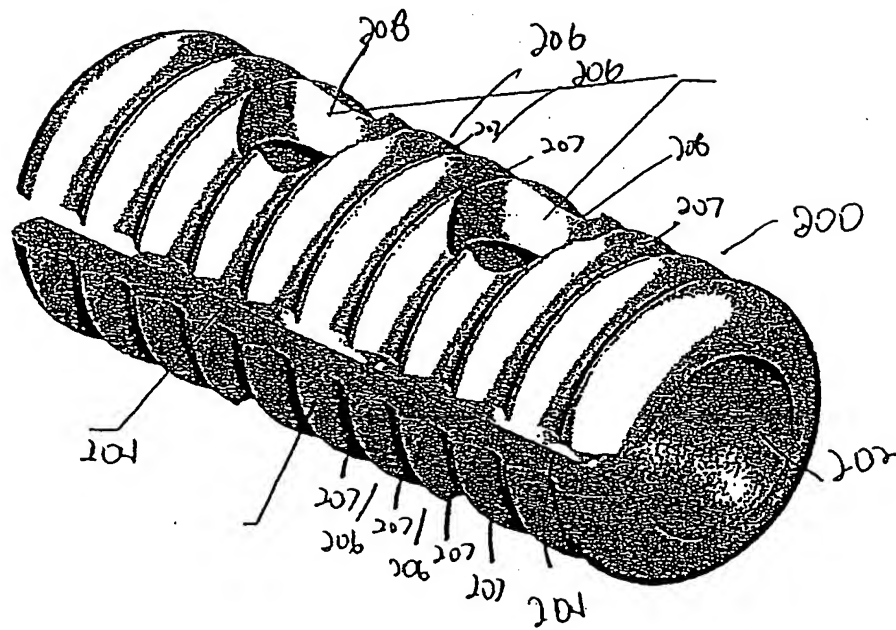


Figure 10



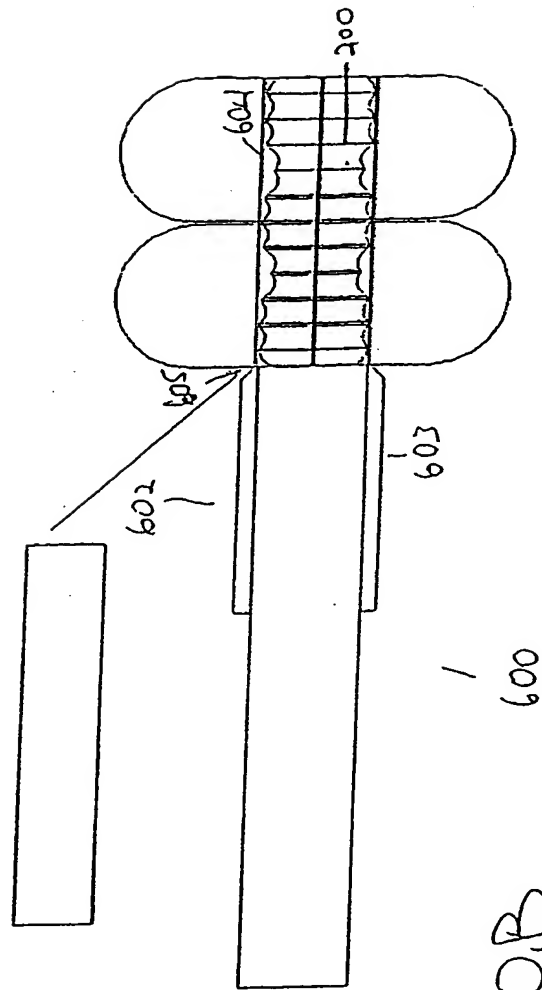


Figure 10B

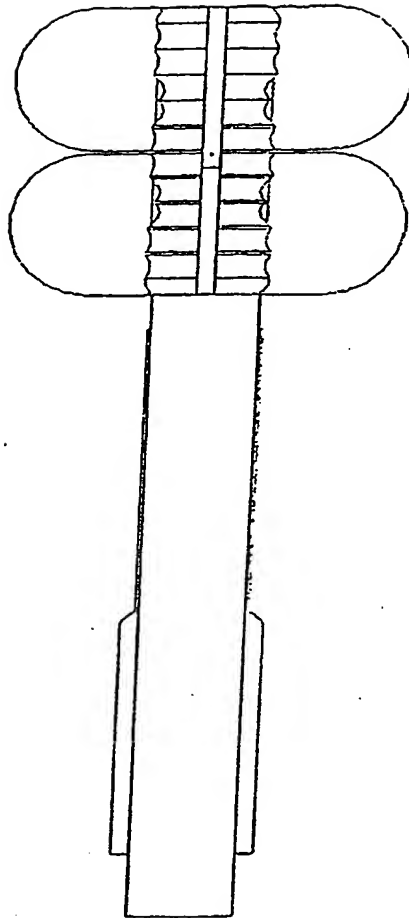


Figure 10C

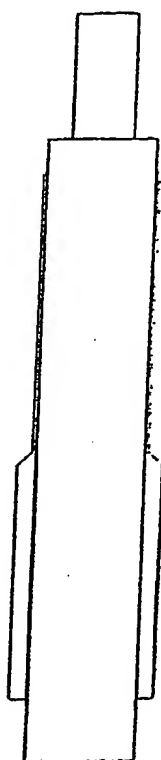
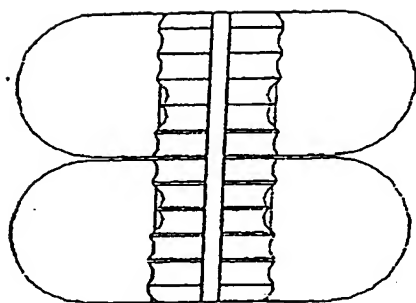


Figure 10D

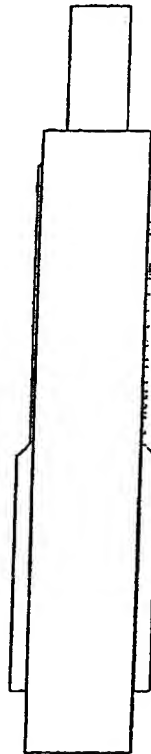
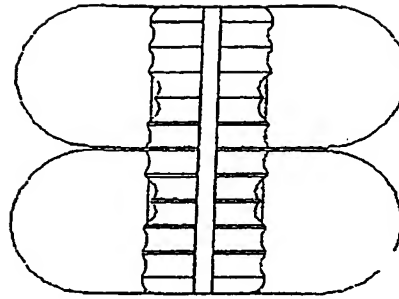
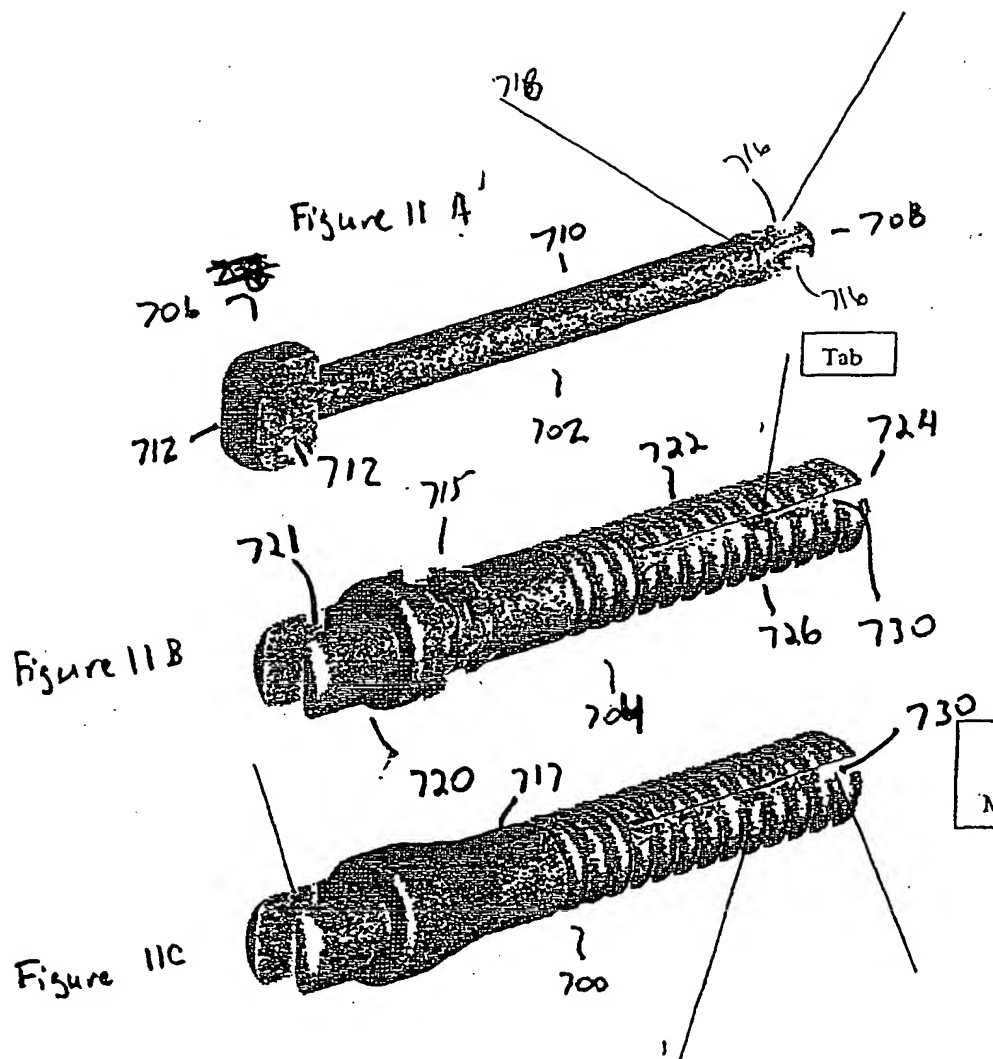


Figure 10E



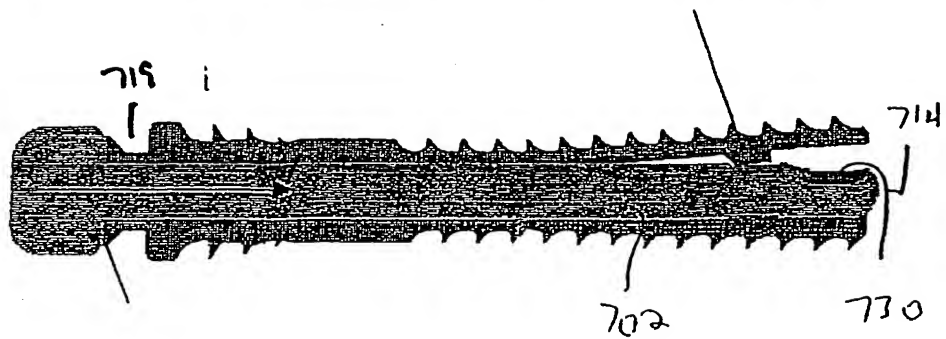
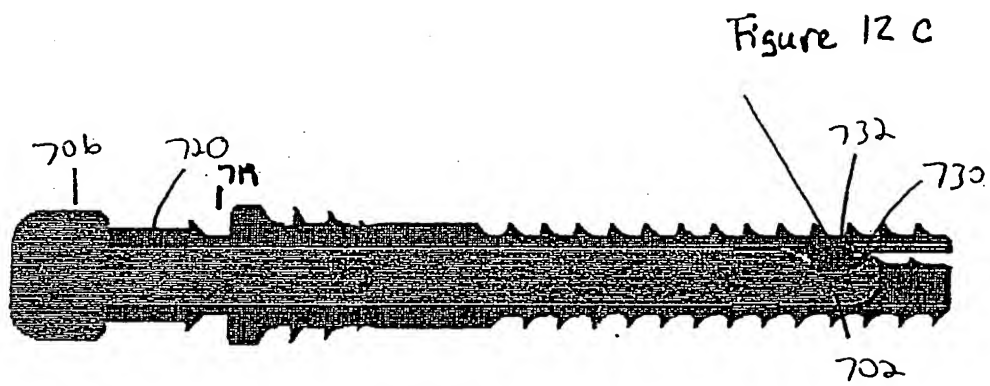
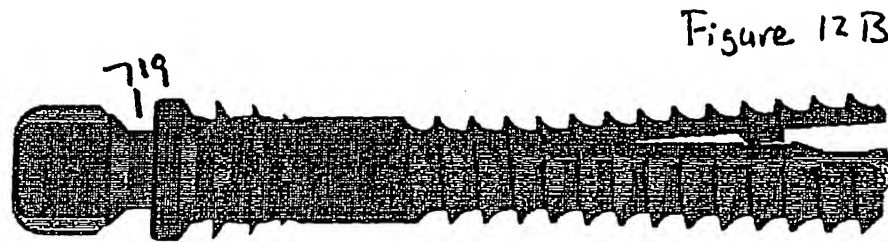
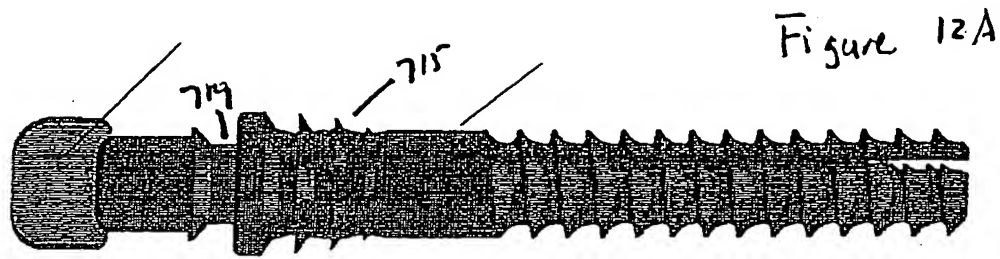


Figure 13 A

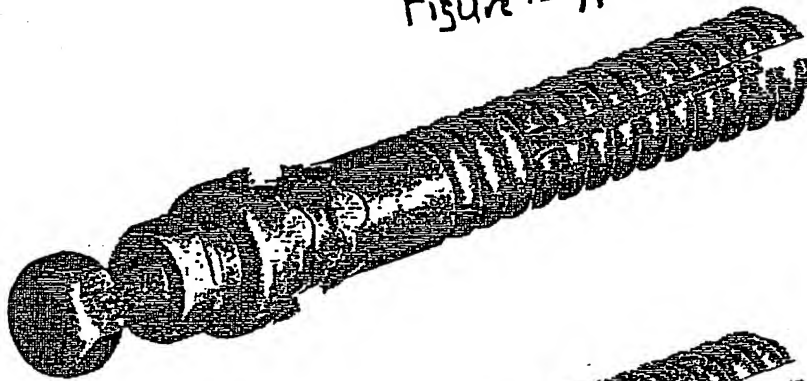
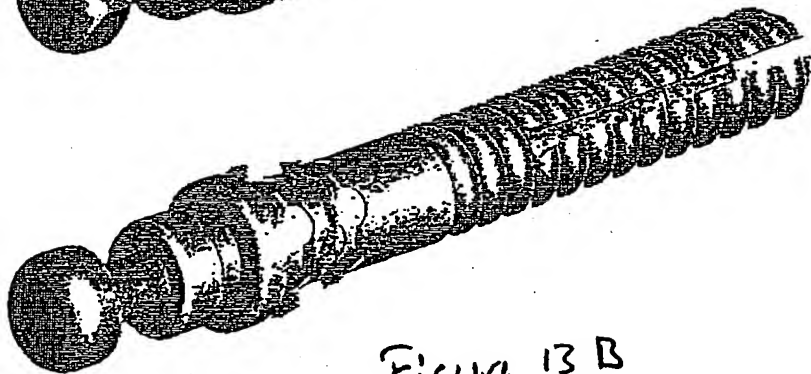


Figure 13 B



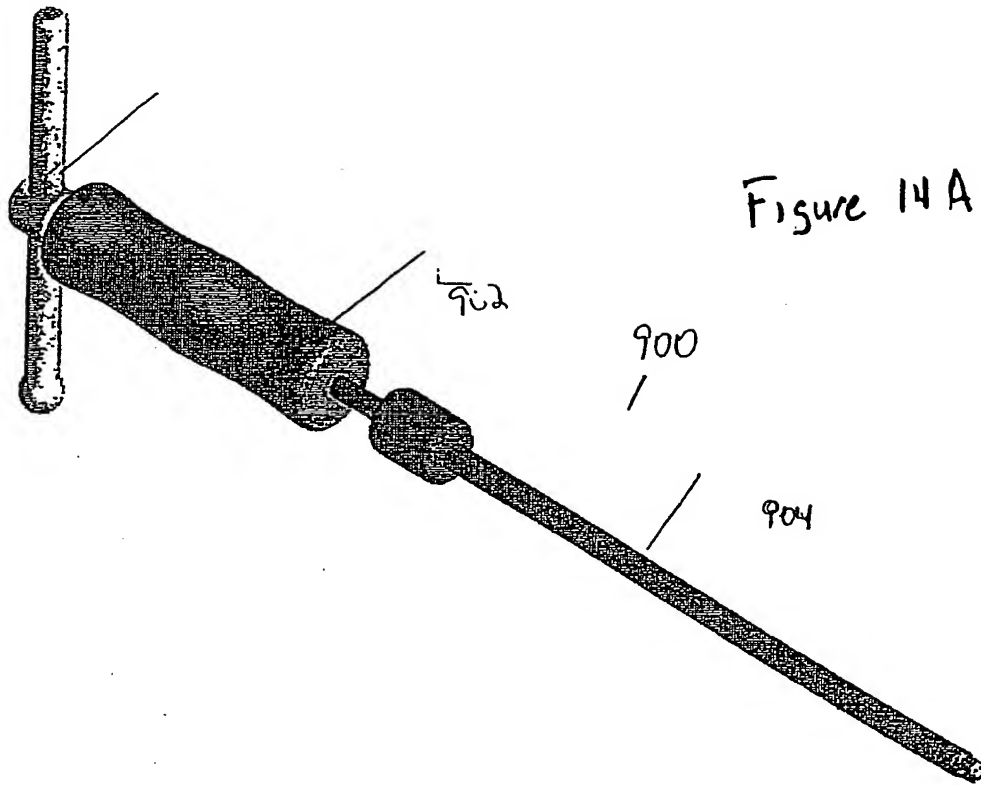


Figure 14B

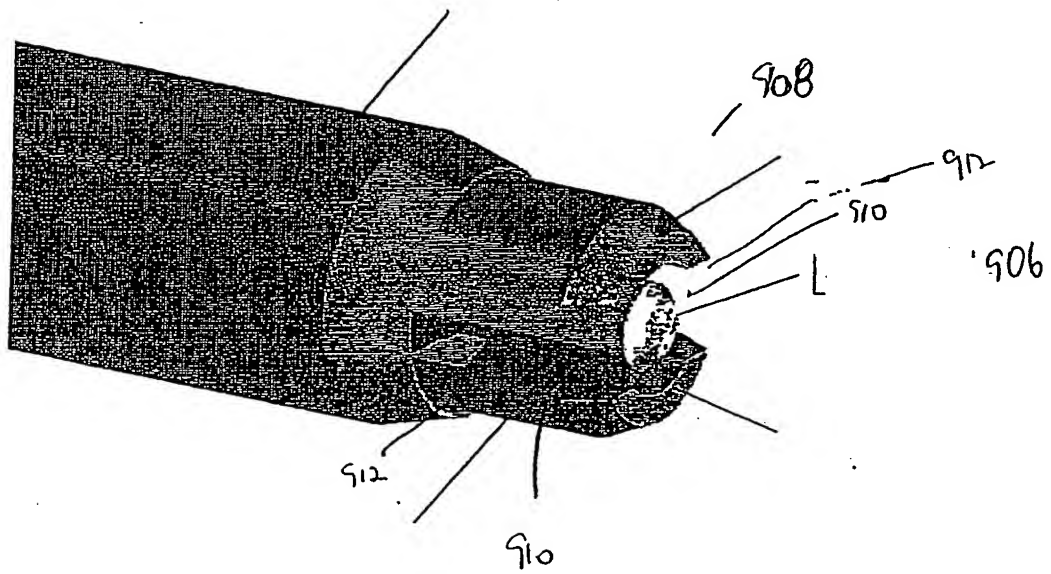


Figure 15

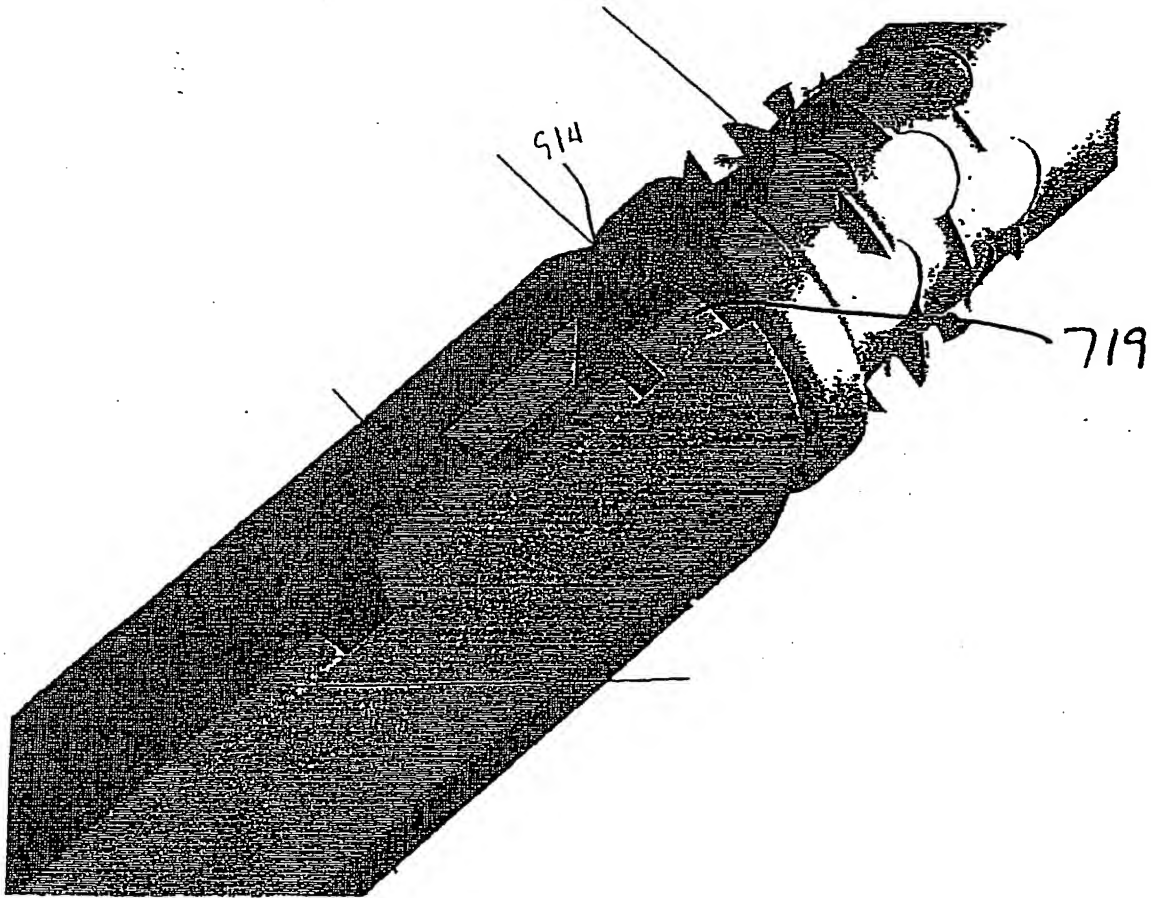


Figure 16

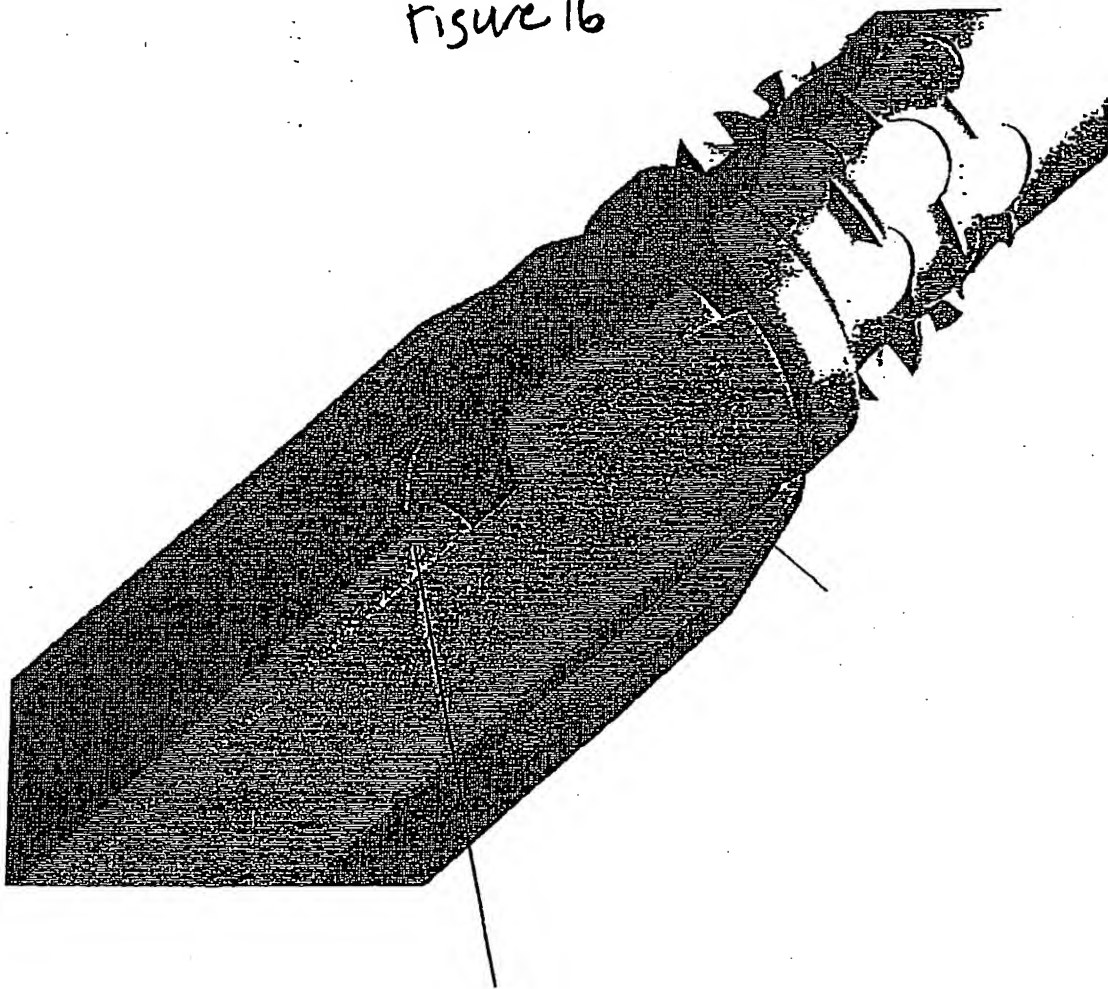
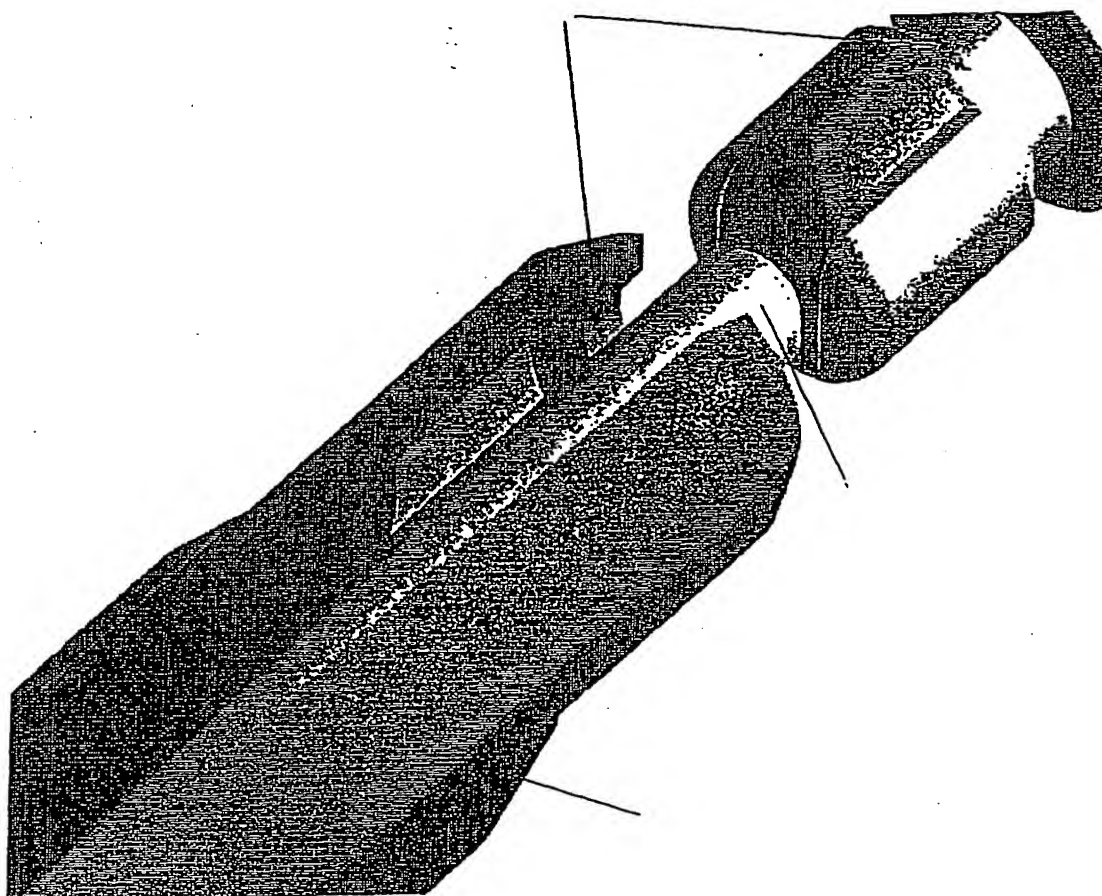


Figure 17



**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.